REMARKS

Summary of the Office Action

Claims 1-24 are pending in this application.

An election of species requirement has been imposed between the following species:

Species I (Figures 1A-1D);

Species II (Figures 4, 5A, 5B);

Species III (Figures 6A-6D, 7A, 7B);

Species IV (Figures 8A, 8B); and

Species V (Figure 9).

Additionally, as Subspecies A (Figure 1A) and Subspecies B (Figure 3) are identified. Applicant has been requested to elect a single disclosed species for prosecution and identify the claims corresponding to the elected species.

Responsive to a telephonic election, Species III, Subspecies A was elected. Claims 1, 2, 5-8, 11, 12, 15, 16, 18 and 21-24 have been examined. Claims 3, 4, 9, 10, 13, 14, 17, and 19 have been withdrawn as directed to non-elected species.

Claims 15, 16, 18, 21, and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 1, 2, 6, 15, 16, 21, and 23 are rejected under 35 U.S.C. § 102(b), as anticipated over Leone et al., U.S. Patent No. 5,882,335 ("Leone").

Claims 1, 2, 6, 15, 16, 21, and 23 are rejected under 35 U.S.C. § 102(b), as anticipated over Globerman et al., International Patent No. 96/26682 ("Globerman").

Claims 5 and 22 are rejected under 35 U.S.C. § 103(a), as obvious over Leone in view of obvious matters of design choice.

Claims 7 and 8 are rejected under 35 U.S.C. § 103(a), as obvious over Leone in view of Harry, U. S. Patent Application No. 2002/0038146 ("Harry").

Claims 1, 11, 12, 15, and 18 are rejected under 35 U.S.C. § 103(a), as obvious over Tower et al., European Patent No. EP 1057460 ("Tower") in view of Globerman.

Claim 24 is rejected over 35 U.S.C. § 103(a), as obvious under Globerman in view of Slepian at al., International Patent. No. WO 90/01969 ("Slepian").

Applicant's Response

Applicant affirms its telephonic election, without traverse, of Species III (Figures 6A-6D, 7A, 7B) for initial examination in this application, and identifies claims 1, 2, 5-8, 11, 12, 15, 16, 18, and 21-24 as corresponding to the elected species.

With respect to the indefiniteness rejection of claims 15, 16, 18, 21, and 22 based on the use of the term "the wire," applicant has amended claim 15 to substitute the term "tube". Applicant submits that this amendment obviates the § 112 rejection.

Applicant has studied the prior art rejections and amended independent claims 1, 15 and 23 to patentably distinguish over the prior art of record. Specifically, claim 1 has been amended to recite that the stent includes "a therapeutic agent ***dispersed within a bioabsorbable polymer, the bioabsorbable polymer*** disposed within the lumen" wherein "... ***the bioabsorbable polymer mediat[es] the delivery of the therapeutic agent over an extended period of time***." Support for this amendment is found in the specification in paragraphs 31 and 48. None of the prior art of record teaches or suggests this combination of features.

As described in the specification, the therapeutic agent preferably is used with a bioasborbable polymer that slowly degrades over a period of time. In this manner, the drug release characteristics of the stent may be modified by selection of the bioabsorbable polymer, without having to change the physical characteristics of the stent, e.g., the dimensions of the lumen or the number or size of the pores. Accordingly, the stent of the present invention may be used in conjunction with any number of therapeutic agents by selecting an appropriate bioabsorbable polymer - without the need to physically alter the configuration of the stent. See specification at 31 and 48.

By contrast, Leone teaches only that "the pores or holes are the size that is small enough to prevent rapid leakage, but large enough to allow slow leakage of solution over a period of several days to weeks." Accordingly, in order to use the stent of Leone with drugs having different viscosities, Leone teaches that the stent manufacturer should adjust the number and size of the holes to achieve the desired release rate. The approach taught by Leone not only requires that those stents be designed using a trial and error approach, but also requires the stent manufacturer to keep an inventory of stents having different physical configurations as required for different drugs.

Globerman does not remedy this deficiency in Leone. On the contrary, Globerman appears to suffer from the same defect as Leone, stating only that "the lumen of the tubular material may contain radiopaque material or pharmacological substance" and that "[t]he wall of the tubing may have one or more small or miniature openings so that such pharmacological substances can be dispersed." Globerman nowhere suggests that a therapeutic agent be dispersed within a biodegradable polymer

such that the rate of release of the agent is controlled by the rate of biodegradation of the polymer, as opposed to the size of the openings.

Harry discloses a stent having a medicinal coating applied thereto to the exterior of the stent. As described in paragraph 41 of Harry, the medicinal coating also extends into "relief cuts" formed on the surface of the stent to "greatly increase[] adhesion of the coating ... to the stent." In addition, having the coating extend into the relief cuts also "significantly reduces the likelihood of the coating separating from the surface of the struts as the stent is expanded." *Id.* The coating may be dissolvable.

In contrast to the present invention, the function of the coating in Harry is to ***bind*** the medicinal substance to the ***exterior*** of the stent, so that the medicinal substance does not spall when the stent is expanded. Nowhere does Harry teach or suggest that a dissolvable coating should be disposed in an internal lumen of a stent to control release of a therapeutic agent through a multiplicity of pores. Leone teaches that the release rate of the drug should be controlled by varying the size of the holes. Applicant submits that Harry provides no teaching that would have motivated one of ordinary skill to have departed from the teachings of Leone when constructing a drug eluting stent where the drug is released from an internal reservoir within the stent.

As acknowledged in the Office action at page 6, Tower provides no teaching relevant to drug eluting stents.

Read in context, Slepian also provides no teaching relevant to the present invention. Contrary to the assertion at page 7 of the Office action, Slepian explicitly ***teaches away*** from the use of metal stents by instead providing a method for endoluminal paving and sealing:

"The present invention provides a solution to the problem of restenosis following angioplasty, ***without introducing the problems associated with metal stents***..."

See page 8, lines 10-25.

In the methods described in Slepian, a balloon having a predetermined shape (referred to as an expansile member") includes a coating or sleeve of a biocompatible polymer. The balloon is disposed within a vessel and then expanded until the coating is impressed from the balloon onto the wall of the vessel, thereby "paving" and "sealing" the vessel. See page 15, line 27 though page 16, line 35 and page 17, lines 13-24. In this manner, a number of patches of different configurations may be applied to a vessel wall, as described with respect to FIGS. 1-8 of Slepian (notably, none of those patches includes a metal stent or stent-like structure).

The Office action states that "Slepian teaches (page 15, lines 33-35) that the bioabsorbable polymer can be delivered via a tubular device, i.e., stent and can be located in the interior of the delivery device, page 19, lines 9-11, 16-18, 25, 26." Applicant respectfully disagrees. Read in context, the "long flexible tubular device" referred to at page 15, lines 33-35 refers to various types of ***catheters*** that could be used for applying the polymer paving to the interior of the vessel wall by "spraying, extruding or otherwise," ***not stents***.

Likewise, the various references at page 19 apply to the configuration of the PEPS coating disposed on the exterior of the catheter balloon do not teach or suggest the use of stents. Instead, they teach exactly the opposite - that the polymer coating may be disposed on the exterior of the balloon in the form of a perforated tube, helical sleeve or discontinuous members of various shapes (lines 9-11). The

polymer coating may be affixed to the exterior of the balloon using a retractable sheath on the delivery catheter (16-18). The polymer coating also may take the form of polymer dots "enmeshed" in a dissolvable mesh substrate as depicted in FIGS. 20 (lines 25-26). The mesh substrate serves merely as a vehicle for carrying the polymer dots, it does not provide any of the mechanical functions associated with a "stent", such as radially supporting a vessel.

In view of the foregoing, applicant submits that none of the foregoing passages would fairly have suggested to one of ordinary skill in the art that "bioabsorbable polymer may be delivered via a tubular device, i.e., stent." To the contrary, the entire teaching of Slepian is directed to ***avoiding the use of metal stents***. In view of that explicit teaching, applicant submits that Slepian would not have suggested to one of ordinary skill to use a biodegradable polymer in conjunction with a pharmacological agent, ***inside a metal stent***, to control release of the pharmacological agent through the pores of the stent.

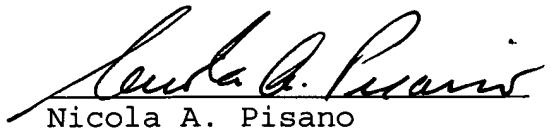
Applicant respectfully submits that amended claims 1, 15 and 23 patentably distinguish over the prior art of record. Accordingly, dependent claims 2, 5-8, 11, 12, 16, 18 and 21 at patentable for at least the same reasons.

In addition, applicant submits that because claims 1, and 15 are generic to all of the disclosed embodiments, withdrawn claims 3, 4, 9, 10, 13, 14, 17, 19 and 20 should be rejoined in this case.

CONCLUSION

In view of the foregoing, applicant respectfully submits that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,



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